IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. HOSPIRA, INC. and PFIZER INC., Defendants.	C.A. No. 18-1064-CFC **PUBLIC VERSION** **Filed December 10, 2019**

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO STRIKE AND PRECLUDE DEFENDANTS' ON-SALE/PUBLIC USE INVALIDITY THEORY

Arthur G. Connolly III (#2667)
Ryan P. Newell (#4744)
Stephanie S. Riley (#5803)
CONNOLLY GALLAGHER LLP
1201 North Market Street, 20th Floor
Wilmington, Delaware 19801
Telephone: (302) 757-7300
Facsimile: (302) 757-7299
aconnolly@connollygallagher.com
rnewell@connollygallagher.com
sriley@connollygallagher.com

Attorneys for Pfizer Inc. and Hospira, Inc.

Of Counsel:

Dimitrios T. Drivas
Alison Hanstead
John Scheibeler
Kevin Georgek
Brigid Bone
WHITE & CASE LLP
1221 Avenue of the Americas
New York, NY 10020
(212) 819-8200

Brendan Gavin
WHITE & CASE LLP
75 State Street
Boston, MA 02109
(617) 979-9300

Dated: December 4, 2019

Dear Judge Connolly:

Defendants Hospira, Inc. and Pfizer Inc. respond to Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited's motion to strike Pfizer's on-sale invalidity defense. Pfizer's defense is simple. Amgen's U.S. Patent No. 9,643,997 ("the '997 Patent") is invalid under 35 U.S.C. § 102(b) because the Pfizer process accused of infringement was the subject of a commercial offer for sale and sale, as part of the sale to the United States company Barr Laboratories, Inc. in 2005, of all U.S. rights to Pliva Croatia, Ltd.'s filgrastim product. This offer for sale and sale occurred more than one year before the earliest effective filing date of the '997 Patent. Pfizer's on-sale bar defense is critical to Pfizer's case and to the invalidity of the '997 Patent.

Pfizer first alleged that the '997 Patent was invalid under the public use provision in 35 U.S.C. § 102(b) on August 23, 2019, before the close of fact discovery. Opposition Exhibit ("Op. Ex.") 1 at 31, 49. Pfizer supplemented its 35 U.S.C. § 102(b)-based invalidity contentions with the on-sale bar in its supplemental invalidity contentions and interrogatory responses dated October 11, 2019, the date that the parties agreed to exchange supplemental contentions and interrogatory responses (D.I. 91 at 1), and over two months before the due date for Amgen's responsive expert reports on invalidity.

The basis for the on-sale bar is an agreement in 2005 between Barr Laboratories, Inc. ("Barr") and Pliva Croatia, Ltd., ("Pliva") and its affiliates, whereby Barr acquired all of the U.S. rights to Pliva's filgrastim biosimilar product and made a $5,000,000 payment to Pliva upon signing. Amgen Ex. 12 at HOS-FILG-01853091, HOS-FILG-01853122; Op. Ex. 2 at HOS-FILG-01852268, HOS-FILG-01852276. As described in Amgen's motion, Pliva was subjected to a number of acquisitions and ultimately the Pliva filgrastim business was acquired by defendant Hospira. None of this subsequent acquisition history is relevant to or negates the on-sale effect of the 2005 transaction. Pliva, pursuant to the 2005 agreement, shipped filgrastim to Barr in the United States more than one year prior to the critical date of the '997 Patent. The batch records describing the process used to make the filgrastim shipped to Barr were produced to Amgen on May 17, 2019. *E.g.*, Op. Ex. 3 at 1. Pfizer's experts compared these batch records to the Pfizer process accused of infringement in their expert reports to conclude that the processes were essentially the same, reduced to practice, and ready for patenting by 2006 at the latest. *E.g.*, Amgen Ex. 3 at ¶¶ 138-76; Amgen Ex. 4 at ¶¶ 206-44.

Courts favor the resolution of disputes on their merits. This is particularly true with respect to the validity of patents. *Abbott Labs. v. Lupin Ltd.*, No. 09-152-LPS, 2011 U.S. Dist. LEXIS 53846, at *13-14 (D. Del. May 19, 2011) (denying a motion to preclude an invalidity defense disclosed for the first time in an opening expert report sixteen weeks after the close of fact discovery where, among other things, Plaintiffs were able to address the invalidity defense in their rebuttal expert reports). Because the "exclusion of critical evidence is an 'extreme' sanction . . . a district court's discretion is not unlimited," and is constrained by the *Pennypack* factors. *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 297 (3d Cir. 2012). The *Pennypack* factors favor denying Amgen's motion and permitting the jury to assess the validity of the '997 Patent on a full record.

***Pennypack* Factor 1: The prejudice or surprise to the party against whom the evidence is offered.** Pfizer timely disclosed its on-sale bar defense on the agreed-upon deadline for supplementing contentions and interrogatory responses. D.I. 91 at 1. As early as May 17, 2019, Pfizer produced documents evidencing the existence of a commercial offer for sale between the legacy Pfizer entity Pliva and U.S.-based Barr. Pfizer's documents described the '"Development, Supply, and Marketing Agreement' set forth between PAM, Pliva, and Barr on March 30, 2005" and contained correspondence from before the critical date between Pliva and Barr transferring from Pliva to Barr "manufacturing instructions . . . and the whole set of batch records" for Pliva's filgrastim drug substance. Op. Ex. 4 at 8, 13, 24; Op. Ex. 5 at HOS-FILG-00745820. Amgen did not seek any further discovery on the 2005 Agreement, including from Pfizer's Rule 30(b)(6) witness on manufacturing issues, Dr. Valinger, notwithstanding his testimony that he became involved in the filgrastim project around 2005 when he was appointed "director of [the] biotechnology department in Pliva," (Op. Ex. 6, Valinger Tr. 36:23-37:1), and that the manufacturing process Pliva employed around the time of the sale to Barr was "almost identical" to Pfizer's current process. *Id.* at 38:3-19. Amgen had evidence of the sale to Barr and cannot be surprised or prejudiced.

***Pennypack* Factor 2: The possibility of curing the prejudice.** Pfizer has indicated that it will provide Amgen with further discovery to cure any perceived prejudice to Amgen. Shortly after receiving Pfizer's supplemental contentions and interrogatory responses, Amgen sought additional discovery in the form of twenty-one 30(b)(6) deposition topics, five interrogatories, and twenty-one requests for production directed exclusively to Pfizer's on-sale bar theory. Op. Ex. 7 at 1, 2-8 (listing discovery requests). Amgen also indicated that "any additional discovery would need to proceed on an expedited basis so as to minimize prejudice and disruption of the case schedule." *Id.* at 1. Pfizer agreed to provide all of the

discovery that Amgen requested within the current schedule. Op. Ex. 8 at 2, 4. Pfizer proposed deposition dates for the twenty-one 30(b)(6) topics on December 5 and 6 (more than ten days before the December 18, 2019 due date for Amgen's responsive expert reports on invalidity). *Id.* at 2. Amgen declined Pfizer's invitation to depose these witnesses. Nevertheless, based on Amgen's initial request for additional discovery, Pfizer searched for, reviewed, and intends to produce today, documents responsive to Amgen's October 23, 2019 discovery requests. Pfizer also remains willing to produce witnesses to testify on Amgen's twenty-one 30(b)(6) topics. Any prejudice to Amgen was cured by Pfizer's willingness to provide the extensive additional discovery that Amgen requested. *See Helios Software, LLC v. SpectorSoft Corp.*, No. 12-081-LPS, 2014 U.S. Dist. LEXIS 97699, at *6 (D. Del. July 18, 2014) ("The prejudice to Plaintiffs can be cured by a short deposition.").

***Pennypack* Factor 3: The likelihood of disruption of trial.** Permitting Pfizer to assert its on-sale bar defense will not delay or otherwise disrupt the orderly resolution of this matter. Pfizer disclosed its on-sale bar defense to Amgen over two months before Amgen's rebuttal expert reports on invalidity are due. Pfizer also made its 30(b)(6) witnesses available for deposition before the due date for Amgen's rebuttal reports. Pfizer's willingness to provide the extensive additional discovery that Amgen requested on an expedited basis minimized the likelihood that the case schedule would be disrupted. *See* Op. Ex. 7 at 1; Op. Ex. 8 at 4.

***Pennypack* Factor 4: Any bad faith or willful deception.** The exclusion of critical evidence is an "extreme sanction" and is not normally imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence. *EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 93 (D. Del. 2016). Amgen has not and cannot claim that Pfizer has engaged in willful deception, flagrant disregard of a court order, or bad faith. It has not. Pfizer timely supplemented its invalidity contentions and interrogatory responses on the agreed-upon date for supplementation. D.I. 91 at 1.

***Pennypack* Factor 5: The importance of the excluded evidence.** Pfizer's ability to present its on-sale bar defense is critical to the jury's ability to assess the validity of the '997 Patent on a full record and furthers the public interest in the validity of patents. *Blonder-Tongue Labs. v. University of Ill. Found.*, 402 U.S. 313, 343-44 (1971).

Pfizer respectfully requests that the Court deny Amgen's motion to exclude critical evidence of the invalidity of the '997 Patent.

Respectfully submitted,

/s/ Arthur G. Connolly, III

Arthur G. Connolly III

cc: Counsel of Record (via ECF)

Attachment 1

CERTIFICATION OF COMPLIANCE WITH THE NOVEMBER 6, 2019 STANDING ORDER REGARDING BRIEFING IN ALL CASES AND THE APRIL 22, 2019 SCHEDULING ORDER FOR PATENT CASES IN WHICH INFRINGEMENT IS ALLEGED

I hereby certify that this letter brief is in 14-point Times New Roman font and that this letter brief complies with the three-page limitation set forth in paragraph 12(b) of the April 22, 2019 Scheduling Order for Patent Cases in which Infringement Is Alleged.

/s/ Arthur G. Connolly, III
Arthur G. Connolly III (#2667)

CERTIFICATE OF SERVICE

I hereby certify that on December 4, 2019, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants. I further certify that I caused copies of the forgoing to be served on December 4, 2019 upon the following by email:

Robert W. Whetzel
Katharine Lester Mowery
Tyler E. Cragg
RICHARDS, LAYTON & FINGER, P.A.
One Rodney Square
920 North King Street
Wilmington, Delaware 19801
(302) 651-7634
whetzel@rlf.com
mowery@rlf.com
cragg@rlf.com

John R. Labbe
Kevin M. Flowers
Mark H. Izraelewicz
MARSHALL, GERSTEIN & BORUN LLP
6300 Willis Tower
233 S. Wacker Drive
Chicago, Illinois 60606-6357
(312) 474-6300
jlabbe@marshallip.com
kflowers@marshallip.com
mizraelewicz@marshallip.com

Jen Gordon
Jennifer Wu
Nicholas Groombridge
Naz E. Wehrli
Peter Sandel
Jacob T. Whitt
Aaron J. Marks
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019-6064
(212)373-3000
jengordon@paulweiss.com
jwu@paulweiss.com
ngroombridge@paulweiss.com
nwehrli@paulweiss.com
psandel@paulweiss.com
jwhitt@paulweiss.com
amarks@paulweiss.com

/s/ Arthur G. Connolly, III
Arthur G. Connolly III (#2667)